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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,460	12/29/1998	MARC R. HAMMERMAN	A-64236-3-RF	3124

7590 12/18/2001

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1653	18

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/222,460	Applicant(s) HAMMERMAN ET AL.	
	Examiner Anish Gupta	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-9,17,20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-9,17,20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Application/Control Number: 09/222,460
Art Unit: 1653

DETAILED ACTION

The amendment filed 10-5-01 is acknowledged. The amendment

1. All rejections made in the previous office action are hereby withdrawn. New grounds for rejections follow below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 states that "the composition is administered to said recipient in a manner such that. . ." Thus the claims indicates a specific mode of administration is desired. However, the claim does not recite mode of administration constitutes this specific "manner" that achieves the specific desired result. Thus the claims is indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Sariola et al.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

The reference teaches that glial cell line derived neurotrophic factor (GNDF) can induce uretic bud formation from the Wolffian duct in the metanephric area (see page 6, lines 17-18 and page 17, lines 5-30). It should be noted

that the reference characterizes as a growth factor (see page 13). Since the reference the cellular growth to the metanephric area, the claims are anticipated by the reference. Although the reference does not teach the limitation of transplantation, such language is an intended use limitation. Intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra.*

5. Claims 1, 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

The reference teaches that mouse metanephroi were exposed to IGF-I (100ng/mL) in an organ culture for seven days. An enlargement of the metanephroi was observed. The reference concludes that IGF-I has a trophic effect on the embryonic kidney during the postinductive period of metanephric development (see abstract). Although the reference does not teach the limitation of transplantation, such language is an intended use limitation. Intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra.*

6. Claims 1 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rogers et al.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

The reference teaches that TGF-α, when administered to the removed metanephroi, was effective in increasing the size of morphological complex of metanephroi. The reference concludes that the peptide is necessary for growth and development of metanephroi in vitro (see abstract). Although the reference does not teach the limitation of transplantation, such language is an intended use limitation. Intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 7-9, 17, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerman et al. in view of Liu et al..

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

Hammerman et al. teach a method of increasing nephon mass of a mammalian recipient comprising implanting at least one whole metanephros of an embryonic mammalian donor next to the recipients omentum (see claims). The difference between the prior art and the specification is that the reference does not teach the administration of a growth factor.

However, Lui et al. teaches that mouse metanephroi, when exposed to IGF-I (100ng/mL) in an organ culture for seven day, resulted in the enlargement of the metanephroi. The reference concludes that IGF-I has a trophic effect on the embryonic kidney during the postinductive period of metanephric development (see abstract). Therefore it would have been obvious s to administer exogenous IGF-I after the transplantation to induce growth and differentiation of the metanephroi tissue.

8. Claims 7-9, 17, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerman et al. in view of Rogers et al..

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The reference teaches that TGF-α, when administered to the removed metanephroi, was effective in increasing the size of morphological complex of metanephroi. The reference concludes that the peptide is necessary for growth and development of metanephroi in vitro (see abstract). Therefore it would have been obvious s to administer exogenous IGF-I after the transplantation to induce growth and differentiation of the metanephroi tissue.

9. Claims 7-9, 17, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolf et al. in view of Rogers et al..

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

Woolfe et al. teach the implantation of metanephric tissue from neonatal mice (see abstract). The reference further indicates the "feasibility of adding functional nephrons to mammalian kidneys in which there is on going nehporgeneiss post-natally" (see abstract). The difference between the prior art and the specification is that the reference does not teach the administration of a growth factor.

The reference teaches that TGF-α, when administered to the removed metanephroi, was effective in increasing the size of morphological complex of metanephroi. The reference concludes that the peptide is necessary for growth and development of metanephroi in vitro (see abstract). Therefore it would have been obvious s to administer exogenous IGF-I after the transplantation to induce growth and differentiation of the metanephroi tissue.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

1/17/01

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